Response to Comments on the Terrestrial Risk Assessment for Ethyl Parathion

Cheminova Comment: EFED should admit that LOC's in the risk index method of risk assessment represent only a screen.

EFED Response: There could be refinements based on technically valid and statistically robust studies that would address exposure and effects uncertainties. However, these refinements would require that a number of uncertainties both for exposure and effects be quantified. This would require that additional data be submitted. The Agency is currently exploring ways to improve ecological assessments (ECOFRAM), to provide a mechanism through which these uncertainties can better be addressed.

Cheminova Comment: "EFED speculates extensively about population and community level effects, but its risk assessment methodology (calculating RQs) is inadequate and inappropriate for drawing any conclusions about such "macro scale" effects. The RQ calculations are most applicable to the individual organism level of biological organization, not higher levels of biological organization."

EFED Response: EFED does not claim the declines were caused by ethyl parathion. The draft RED chapter states, "While these data do not establish causality for population declines (a variety of factors are likely to contribute to population declines), they do suggest that populations of many bird species at a state-wide level of resolution could be sensitive to additional acute or reproductive effects from exposure to ethyl parathion."

Studies discussed in the draft RED detail avian reproductive effects caused by short-term exposure to levels of ethyl parathion expected to occur in treated fields. However, the population data presented pertain to species associated with cotton fields. Since cotton accounts for a small percentage of total ethyl parathion use, and is used on cotton in only three of the states presented in the Breeding Bird Survey table, little value is added to the ethyl parathion risk assessment by its inclusion. It will be removed from the final RED chapter.

Cheminova Comment: EFED's avian and mammalian risk assessments assume that animals will eat only one kind of food, and that all of the food consumed will be contaminated with ethyl parathion at the maximum initial estimated residues.

EFED Response: The current risk assessment method for terrestrial organisms was designed to account for uncertainties. Because of the uncertainty, the method includes some conservative assumptions. In some aspects, such as those described above, conservative assumptions are made that will tend to over-estimate exposure. However, in many other aspects, assumptions are made and factors are overlooked that may

cause the risk to be underestimated. For example, all routes of exposure other than ingestion of contaminated food are ignored, and animals in the wild are assumed to consume food at a rate no greater than those kept in captivity. Overall, the Agency does not believe that the risk assessment is inappropriately conservative. The Agency is working on developing risk assessment methods that will address some of these factors. The Agency is open to receiving data from Cheminova which further explores consumption patterns of terrestrial organisms in the wild.

Cheminova comment: EFED's primary criterion for selecting toxicity endpoints appears to be limited to finding those studies with the lowest toxicity values, and then using those values to calculate point estimate risk quotients for various groups of organisms. For multiple reasons, Cheminova believes that this approach to toxicity endpoint selection is inappropriate, particularly when a large database is available for a compound. They "calculated mean values and 95 percent confidence limits using standard statistical procedures; the value of the lower 95 percent confidence limit was selected as the dietary toxicity endpoint." Cheminova separated quail and mallard chronic toxicity data in their assessment because the toxicity values for these are different by an order of magnitude. They compared mallard data to grass and leaf EECs, and quail data to insects and seeds/fruits.

EFED Response: Only two bird species are tested, one waterfowl species and one upland game-bird species, under the Fish and Wildlife Data Requirements listed in CFR 158. There is a great deal of uncertainty associated with extrapolating from the acute oral and subacute dietary data from two species to the large numbers of bird species associated with agricultural areas. Our ecological risk assessments assume that if we use the most sensitive tested species in the laboratory, then we provide some protection to untested species in the environment.

Field surveys indicate that a large variety of birds are associated with agricultural systems. The EFED ecological database indicates that there can be a large variation in sensitivity to a chemical between species. Using the most sensitive species tested and upper limits of estimated environmental concentrations to calculate risk is a reasonable way to compensate for this uncertainty in the toxicity data.

The basis for Cheminova's approach to data evaluation for selecting toxicity endpoints is not clear. They indicate that the entire data set should be considered and that this is done by calculating the mean values and the 95% confidence limits using standard statistical procedures. The value of the lower 95% confidence limit was then selected as the dietary toxicity endpoint. Cheminova's approach appears to assume that toxicity estimates are not species specific, allowing the pooling of data. However, they separate the mallard from other species due to its very distinct difference in sensitivity. This would suggest that the pooling of toxicity data would be inappropriate for the other species as well, but no explanation is given beyond the difference in sensitivity. This difference in sensitivity, however, is one of the main reasons that pooling of toxicity data is inappropriate and can lead to erroneous conclusions in the assessment of risk.

Cheminova Comment: EFED's risk assessment should give greater weight to higher quality studies. Studies using Cheminova's test material should be given more weight. Modern ethyl parathion has fewer impurities.

EFED Response: All of the studies used to determine toxicological endpoints were reviewed by EFED or HED scientists and determined to be scientifically valid. In that way, we ensure that scientifically sound data are used in our assessment. Open literature studies are cited to provide supplemental information that enhances our assessment.

The guidelines for assessing whether the purity of the test substance is adequate are detailed in Subdivision E, which was published in 1982, found to be adequate in the Rejection Rate Analysis of 1994, and are still current today. Therefore, the scientifically valid studies that were used in EFED's assessment were performed with test substance of sufficient purity by current standards.

The "Industry Comment" on this subject in the Rejection Rate Analysis states:

> "Industry agrees that the guidance documents provide appropriate guidance, and that knowledge of the purity of the test substance is mandatory for a risk assessment. However, not all impurities may have to be known, unless there is reason to suspect the influence of impurities."

Cheminova Comment: "Based on the very short environmental persistence and small number of applications of ethyl parathion (one or two in a short time period) that typify the way this product is used, Cheminova does not believe that potential chronic exposure of wildlife to ethyl parathion occurs. The vast majority of uses result in short-duration exposure scenarios, lasting from 1 to 6 weeks. Even under the maximum application scenarios, which involve up to 6 applications to a crop, the duration of the exposure scenario is only about 4 to 7 weeks because the applications occur over very short intervals (5 to7 days) under these maximum application scenarios. In actual practice, however, ethyl parathion is rarely applied more than twice per season. Moreover, ethyl parathion dissipates rapidly following the final application. Thus, the "longer-term" exposures are most appropriately considered subacute to subchronic exposures.**"**

EFED Response: Existing toxicological studies are limited in their ability to distinguish between latent expression of adverse effects from short exposures and those effects requiring more protracted exposure for expression. In other words, the available toxicity studies can not determine how long organisms must be exposed before effects occur. In addition, data from the open literature suggest that the close chemical analog methyl parathion may cause long-term effects through endocrine disruption, further exemplifying the limits in the ability of existing toxicity studies to distinguish latent expression of adverse effects from short exposures.

Cheminova comment: "EFED has claimed that reproductive effects may occur following exposures much shorter than those used in standard avian reproduction testing (e.g., several weeks), based on articles by Bennett *et al.* (1990, 1991), but EFED has not considered the test concentrations used in those studies. Cheminova previously noted (see Cheminova's comments on EFED's methyl parathion draft RED chapter) that based on the toxicity data table included in the draft methyl parathion RED chapter, EFED appears to have misinterpreted the Bennett *et al.* (1990) study, possibly by confusing results presented as regression analyses with results presented using comparative means testing procedures."

EFED response: As noted in EFED's response to the methyl parathion comments, EFED has reevaluated the study cited as Bennet et al. (1990) in the draft methyl parathion RED chapter and agrees that the results presented in the cited study regarding reproduction effects in birds are based on regression analysis and not the typical means testing used by EFED to establish no observed effects levels (NOEL) or lowest observed effect levels (LOELs). However, this study is not the only reported short-term methyl parathion reproduction study conducted in 1990. Bennet and Bennet (1990) report on a short-term reproduction study involving an 8 day *ad libitum* exposure of egg-laying bobwhite quail (8 per control and 6 per each treatment) to dietary concentrations of methyl parathion (0, 14, 20, 28, and 40 ppm). The results of this study are compatible with means testing and indicate a significant ($p < 0.05$) reduction in egg production relative to controls at the 14 ppm treatment level. The results of Bennet and Bennet (1990) suggest that reproductive effects can indeed occur as a result of short-term exposure to dietary concentrations of methyl parathion close to the LOEC (15.5 ppm) established for the current long-term exposure avian reproduction study (MRID 41179302). Consequently, the registrant's reference to the very high dietary concentrations of methyl parathion (400 ppm) reported to be associated with short-term exposure reproduction effects in mallards from Bennet and Williams (1991) as a refutation of the reasonable possibility for short-term exposure effects on reproduction appears to be moot.

Although ethyl parathion and methyl parathion are very similar chemicals, EFED recognizes the uncertainty associated with the doses of each chemical that might cause the effects seen in the Bennet papers. However, Rattner, et al., 1982 includes data which indicate that short-term exposure to ethyl parathion can also cause reproductive effects at concentrations below EECs described in the RED. Rattner et al. observed statistically relevant ($p < 0.05$) dose-dependant reduction in egg-production, food intake, weight loss, ovary weight and brain acetyl-cholinesterase activity in bobwhite quail after 10 days of exposure to 0, 50, 100, 200 or 400 ppm of ethyl parathion. None of the birds fed doses of 100 ppm or more laid eggs after day 7 of the experiment.

In a second experiment, birds were fed 0, 25 or 100 ppm of ethyl parathion *ad libitum* for 10 days, and a pair-fed control group was fed the same amount eaten by the 100

ppm-fed birds. No reproductive effects (egg-laying and follicular diameter) were seen in the 25 ppm-fed birds nor in the pair-fed group, but statistically relevant ($p < 0.05$) reductions were seen in the birds fed 100 ppm ethyl parathion. Therefore, the authors concluded that the effects seen in the 100 ppm-fed birds were due directly to the chemical exposure, and not to the loss of appetite caused by the exposure. When taken in conjunction with the first experiment, effects can be seen from short-term exposure to 50 ppm, but not with exposure to a 25 ppm dose of ethyl parathion. Since birds were fed *ad libitum* for the full 10 days, it is not clear whether a lesser amount of dosed food early in the experiment might have caused observable effects.

Cheminova Comment: Cheminova requests that EFED provide references supporting its estimated daily feed consumption values as a percentage of body weight, particularly because EFED's estimates of daily feed consumption are much higher that values typically found in the published literature, including values referenced in EFED's 1986 Ecological Risk Assessment Standard Evaluation Procedure and EPA's 1993 Wildlife Exposure Factors Handbook.

EFED Response: EFED has used the allometric equation from Nagy (1987) for dry weight ingestion rates as follows:

$$\text{ingestion rate (dry weight, g/day)} = 0.621\ (\text{body weight g})^{0.564}$$

Contrary to Cheminova assertions, this equation is presented in the USEPA (1993) *Wildlife Exposure Factors Handbook* (equation 3-8, page 3-6). Because this equation yields a body-weight dependent estimate of ingestion rate in terms of dry-weight for the food item, an adjustment must be made to account for the fresh-weight food item encountered by wildlife in the field. This is accomplished through the following equation:

$$\text{ingestion rate (wet-weight, g/day)} = \frac{0.621\ (\text{body weight g})^{0.564}}{1 - \text{fraction water content of food item}}$$

EFED has assumed the following fraction water contents for the various diets:

herbivore diet:	80 % water
insectivore diet:	80 % water
granivore diet:	10 % water

These assumptions of water content are supported by data presented in the USEPA (1993) *Wildlife Exposure Factors Handbook*

Dietary Items	Water Content
forage:	young grasses 70 % - 88 % (Table 4-2, USEPA 1993)
	dicot leaves 85 % (Table 4-2, USEPA 1993)

terrestrial invertebrates:	earthworms 84 % (Table 4-1, USEPA 1993)
grasshoppers/crickets	69 % (Table 4-1, USEPA 1993)
beetles	61% (Table 4-1, USEPA 1993)
seeds:	9.3 % (Table 4-2, USEPA 1993)

Using the Nagy (1997) allometric equation and a herbivore dietary water content of 80% the following fresh-weight dietary mass and percentages of body weight are calculated

Herbivore Body Weight	Daily Ingestion	% Body Weight Ingested
15 g	14.3	95.3
35 g	23.1	65.9
1000 g	152.8	15.3

Using the Nagy (1997) allometric equation and a herbivore dietary water content of 10% the following fresh-weight dietary mass and percentages of body weight are calculated

Herbivore Body Weight	Daily Ingestion	% Body Weight Ingested
15 g	3.18	21.2
35 g	5.13	14.6
1000 g	34.0	3.4

These food ingestion rate and percent of body weight values are consistent with the values used in the ethyl parathion draft RED.

Cheminova Comment: According to two of Cheminova's citations (Brewer, et al., 1997; Fischer, et al., 1997), residues on insects will be one or two orders of magnitude less than would be estimated by grouping insects with plant feed items. In addition, insects should not be used to consider longer term risk, as the treated insects will not be available as a feed item longer-term.

EFED Response: In 1986 EPA established the Standard Evaluation Procedure for ecological Risk Assessment (EPA-540/9-85-001). This procedure used the Hoerger and Kenaga (1972) data for residues on forage as an estimate for small insects. This decision is supported by the position of Kenaga (1973), which states:

"Initial residues on insects are probably in the same order as those on plants of similar surface area to mass ratios..... Most of the factors which affect the decline of residues on plant surfaces are also operative for insect surfaces and so inert residues may be estimated on the basis of insect species having a surface to mass ratio similar to those of equivalent plant type...."

Kenaga (1973) goes on to develop categories of residues with groupings of residue equivalency that include dense foliage and insects together as well as seeds, fruit, and large insects together. Kenaga's (1973) findings have been applied to the data summarized by Fletcher et al. (1994), yielding the present RED document assumptions of residue equivalence between broadleaf/forage plants and small insects as well as between fruits, pods, seeds, and large insects.

EFED is open to consideration of any technically valid and statistically robust studies of residues on avian food items. The studies cited by the registrant were not specific to ethyl parathion. Therefore, they will be considered in the future with the full body of available exposure data as EFED refines its exposure assessment processes.

Although there is additional uncertainty concerning chronic exposure to contaminated insects as feed, it is not inappropriate to estimate this potential risk for ethyl parathion. First, most labeled uses of ethyl parathion provide for multiple applications, which can lead to de facto opportunity for chronic exposure. Second, as detailed in the RED chapter and in this comment response, ethyl parathion has been observed to cause reproductive effects in birds from short-term exposure.

Cheminova Comment: “Preliminary review of residue data for ethyl parathion applications to corn, sunflowers, winter and spring wheat, and alfalfa indicates that the high-end estimated residues relied on by EFED for evaluation of potential risk to birds and small mammals significantly overestimate potential exposure of these non target organisms.”

“Ethyl parathion 8EC was applied to (sic) six times to field and sweet corn at five-day intervals at a rate of 1.0 lb. a.i./A.....Day 0 residues on forage ranged from 5.57-33.1 ppm and day 6 residues on forage ranged from 0.18-8.12 ppm for applications using ground equipment. Residues from aerial applications were slightly lower, with day 0 forage samples ranging from 5.4-11.4 ppm, and day 6 forage samples ranging from 0.16-0.26 ppm. In contrast EFED estimates residues arising from a single 1.0 lb. a.i./A application to be 135 ppm.....using EFED’s multiple application methodology without considering residue dissipation results in estimated residues following six applications of 810 ppm...an error in estimated residues of approximately 25-fold greater than the highest measured value.”

“Ethyl parathion 8EC was applied to sunflowers three times at five-day intervals using a rate of 1.0 lb. a.i./A.....Day 0 forage samples from ground applications contained ethyl parathion residues ranging from 2-67 ppm; day 0 forage samples from aerial applications contained ethyl parathion residues ranging from 4.2-66.8 ppm....”

“The residue data also provide important additional information relative to EFED’s hypotheses concerning residues of ethyl parathion on avian and mammalian feed items. First, the actual measured values show no indication of residue build-up with

multiple applications; residue build-up with multiple application is a key tenant of EFED's assumptions concerning estimated residues on avian and mammalian feed items.....”

EFED Response:

While the available data on field and sweet corn and sunflowers discussed in the registrant comment may have some limited applicability to the broadleaf forage reside category, they are not applicable to the short and long-grass residue estimates performed by EFED. Even if the data were a compelling argument for a reduction in time-zero residues in the broadleaf forage category, the risks associated with short and long-grass residue categories still exceed the EFED acute high risk level of concern for birds. Moreover, incident data do show that use of ethyl parathion can result in avian mortality.

EFED has looked at the corn residue data to determine its applicability to the broadleaf forage residue category. EFED believes that the corn and sunflower residues cited by the registrant are for residues corresponding to whole plant analyses (forage) and are consequently of limited representation for the leaf-only food item assumed in the EFED exposure model. The inclusion of corn and sunflower stem material (of likely greater density when compared to leaves, but of likely lower efficiency for interception of deposited pesticide) would likely result in underestimates of residues for leafy forage. Moreover, there are other data sets available for ethyl parathion residues that suggest that the EFED assumption of 135 ppm/ lb. a.i./acre is not a gross overestimation. Data contributing to the development of the Hoerger and Kenega nomogram include (1) apple leaf residues of 250 ppm following application of ethyl parathion (2.5 lb. a.i./A) with a residue concentration normalized to 1 lb. a.i./acre of 100 ppm and (2) turnip green residues of 103 ppm, when normalized for 1 lb. a.i./acre. In fact, the most recent reported incidents of bird mortality show that ethyl-parathion residues in the crop content of morbid birds have been measured at levels as high as 75 ppm. These residue measurements are likely an underestimate of the actual food item residues prior to consumption, yet are still in excess of the maximum corn or sunflower residues present by the registrant as rebuttal for EFED exposure assumptions.

EFED believes that registrant's contention that the residue data (presumably the corn and sunflower data discussed by the registrant) show no indication that residue build-up is a mischaracterization of the purpose of the residue studies. The data discussed by the registrant deal solely with the residues on crop following the last pesticide application. No residue samples were taken following each consecutive application, so no trend toward accumulation can be evaluated by these data sets. However, if a dissipation half-life of 2.1 days is assumed for ethyl parathion as suggested by available literature data, then approximately 20% of the residues from each previous application would still be on the plant at the time of the next application.

With respect to the discussion of multiple application exposure modeling scenarios

employed by EFED, it should be noted that all avian risk quotient calculations for ethyl parathion were performed on the basis of a single application at label rates. EFED has not suggested that multiple applications would result in higher risk quotients with each successive application. Indeed, the corn residue data suggest a fairly rapid dissipation rate for that particular crop. However, the fact that multiple applications of the pesticide are allowable under the present labels suggests that the risks from a single application may be more likely to realized over considerable proportion of the growing season as a result of each additional application of chemical**.**

Cheminova Comment: The actual measured values in the field trial data "show no indication of residue build-up with multiple applications".

EFED Response: The field trial data provides no basis for this claim. The day 0 samples in these trials were taken only after the final application had been made. Since samples were not taken after each application, it is not possible to determine whether residues from previous applications persisted and were reflected in the day 0 concentration.

Cheminova Comment: "EFED includes a list of avian incidents to support its claims concerning effects on birds. EFED supplied only minimal information in its appendix listing these incidents; Cheminova requests that EFED supply the full incident reports. However, just from the information that EFED provides, many of these incidents (more than half) either occurred before ethyl parathion became a restricted use pesticide, involved intentional poisoning of wildlife, or involved application inconsistent with the label. Others appear to involve other chemicals, or non chemical causes, and therefore are irrelevant. Cheminova does not believe that this is due to a lack of vigilance by EPA, Fish and Wildlife inspectors, state Game wardens, or others, or to an inability of people to notice and report any avian incidents; rather, Cheminova believes this is due to improved education of certified applicators, and heightened awareness by applicators that any misuse is likely to be noticed and reported."

EFED Response: While it is possible that improved awareness by applicators since 1991 may result in more careful use of a pesticide, EFED cannot ignore avian mortality incidents involving dietary exposure to ethyl-parathion that have occurred subsequent to 1991. Moreover, EFED believes that measures undertaken to mitigate worker health risks my limit opportunities for observation of avian mortality and other effects in treated fields For example, extended post application entry intervals, would likely allow additional opportunity for scavenging of moribund birds in treated fields before in-field observation could occur.

Bee Comments:

Cheminova Comment: "EFED claims an extensive, well-documented history of bee kill incidents. However, EFED's appendix supporting this claim lists only seven incidents,

occurring between 1983 and 1988. . .Cheminova requests that EFED provide it full reports concerning the kill incidents."

EFED Response: The draft RED stated that "incident reports confirm bee kills from ethyl parathion use on sunflowers and alfalfa/wheat." While the incidents included in the appendix predate the 1991 agreement, they are associated with currently labeled crops. In a test cited in the chapter, ethyl parathion was seen to cause 100% mortality in bees at rates as low as 0.5 lb. ai/acre. Current "typical" use rates suggested by Cheminova are all equal to or greater than this rate.

Cheminova Comment: "Cheminova believes that current label language concerning toxicity of ethyl parathion to bees is sufficient. According to the information supplied by EFED, only a small number of incidents have occurred, the last in 1988. Therefore Cheminova concludes that the current label warning, coupled with educational efforts for applicators and dialog with beekeepers, has worked, and there is no need to revise the label language.

EFED Response: After deliberating with the State Labeling Issues Panel (SLIP), the Agency is currently working with Association of American Pesticide Control Officials (AAPCO) and SFIREG (in conjunction with AAPCO) to develop label language describing hazard to bees. In the near future, the Agency will present this proposed language to stakeholders for their input. Since ethyl parathion is toxic to bees, and has caused bee kill incidents in the past, the label language that is adopted should be incorporated onto the ethyl parathion product labels.

Cheminova Comment: "Cheminova does not agree with EFED's hypothesis that human incidents are directly applicable to wildlife because there are numerous considerations unique to the human exposures in these incidents that are irrelevant to potential wildlife exposures."

EFED Response:

EFED does not agree with the position that humans can't be considered as surrogates for potential effects to wildlife on a number of points. First, the toxicological database used to assess mammalian wildlife risks originates from the toxicological database used to define human health risk concerns. Second the mechanism of action of ethyl parathion, like many organophosphates, is conservative across a variety of vertebrate organisms, including humans. Third, risks to humans have been of demonstrable importance to require mitigation measures for reduction in exposure (e.g., post application entry intervals and personnel protective equipment), yet these measures are not available to nor realistic for wildlife using treated fields and surrounding areas subject to drift for food, cover, and water sources. Fourth, the differences between human and wildlife exposures are such that it can be reasonably expected that wildlife residing in treated areas; eating treated food items that are not subject to post

application harvest intervals established for human consumption; incidentally consuming treated soil; and drinking water directly associated with treated areas may be subject to higher dose levels than humans. This latter point is especially important given the greater mass of a human when compared to the many small bird and mammal species associated with agroenvironments.

Response to Comments on the Aquatic Risk Assessment for Ethyl Parathion

A. GENERAL COMMENTS

Cheminova Comment: Although EPA solicited input from agricultural experts on the typical rates of ethyl parathion likely to be used in the field, “unrealistic” maximum label rates were used for the risk assessment. “EFED modeled only maximum use scenarios, and did not model any typical use scenarios. Based on information from growers and extension agents concerning actual use of ethyl parathion, Cheminova intends to have the typical (actual) use patterns for ethyl parathion become equivalent to the maximum use patterns.” The use of “realistic product use scenarios” should be expected “to significantly reduce or completely eliminate the aquatic risk concerns currently envisioned by EFED. "

EFED Response: The information gathered from agricultural experts is instructive for the characterization of potential risk from the use of ethyl parathion. For those species, such as freshwater fish, for which the RQs are not well beyond LOCs, consideration of typical rates may help in evaluating the uncertainty of the risk assessment. In addition, knowledge of application rates most likely used in the field are useful when considering possible mitigation by reduction of the “unrealistic” maximum label rates.

Until the maximum label rates are reduced, however, EFED will use extant maximum rates in our risk assessments. These maximum rates are those supported by the registrant for establishment of tolerances. Registrants are free to reduce maximum label rates without submitting additional data to the agency.

Certain areas of the ethyl parathion use area for a particular crop are likely to be more prone to severe infestation than the “typical”, and therefore the maximum rates might be used more often. Using the maximum rate which can legally be used for a particular crop is the only way to ensure that environmental resources are protected throughout the use area. EFED stands by the use of maximum label rates in its risk assessment.

Since Cheminova has indicated its willingness to change the maximum use rates on ethyl parathion labels, EFED performed PRZM-EXAMS simulations using these “typical” numbers of annual applications. Simulations were run for corn, cotton and sorghum, but not for soybeans (“typical rate” same as maximum) nor alfalfa (“typical”

number of applications poorly defined.)

ETHYL PARATHION TIER II ESTIMATED CONCENTRATIONS CALCULATED USING MAXIMUM USE RATES AND TYPICAL USE RATES						
Crop	**Corn**	**Cotton**	**Sorghum**	**Corn**	**Cotton**	**Sorghum**
State	**Georgia**	**Texas**	**Kansas**	**Georgia**	**Texas**	**Kansas**
Application Rate (lb. ai/acre)	0.75	1.00	1.00	0.75	1.00	1.00
Number of Applications	6	6	6	2	2	1
Interval Between Applications (Days)	5	7	7	7	7	7
Acute (Peak) Conc.	39.8 ppb	54.7 ppb	60.9 ppb	14.3 ppb	20.8 ppb	8.5 ppb
96 Hours Conc.	35.3 ppb	48.4 ppb	53.7 ppb	12.7 ppb	18.6 ppb	7.5 ppb
21 Day Conc.	25.7 ppb	33.1 ppb	37.4 ppb	8.4 ppb	12.5 ppb	5.5 ppb
60 Day Conc.	13.4ppb	20.2 ppb	22.3 ppb	4.4 ppb	7.9 ppb	3.3 ppb
90 Day Conc.	11.4 ppb	15.8 ppb	17.6 ppb	3.6 ppb	5.7 ppb	2.5 ppb
Chronic (Yearly) Conc.	3.9 ppb	5.3 ppb	5.4 ppb	0.84 ppb	1.1 ppb	0.45 ppb

As would be expected, a reduction in the maximum annual number of applications leads to a significant reduction in the expected environmental concentrations. These should not be considered for risk management purposes until Cheminova commits to the proposed label changes. Chemical parameters used in the modeling of ethyl parathion are provided in Table (10) in the RED chapter.

Cheminova Comment: The “structure” of the PRZM/EXAMS modeling system is “inappropriate”. The scenario represented by the models is “not an accurate reflection of a watershed large enough to support a drinking water facility.”

EFED Response: EFED uses PRZM-EXAMS modeling as a screening tool in an attempt to efficiently determine which pesticides will *not* pose a risk to people through drinking-water exposure. If the modeling results suggest a potential for drinking-water concerns,

EFED will further evaluate the results in the context of available water monitoring data. The risk characterization in the ethyl parathion RED chapter includes a detailed comparison of the results and uncertainties of the modeling and monitoring.

EFED has encountered a number of cases where monitoring data for ecologically important surface water were in excess of concentrations predicted by the 1-hectare pond scenario. In addition, EFED conducted a comparison of contaminant predictions for the field pond scenario and an index reservoir of larger surface area, volume, and drainage area for presentation to the July, 1998 SAP. Predicted concentrations of hypothetical uses of selected pesticides were higher in the index reservoir than in the 1-hectare pond simulated by PRZM-EXAMS.

Cheminova Comment: EFED admits that PRZM 3.1 is not validated, which calls the model predictions into question.

EFED Response: Validation of the surface water models is problematic because there are insufficient data on pesticide concentrations in surface waters. EFED is addressing the model evaluation issues using the following approaches: 1.) OPP and USGS are conducting a pilot nationwide monitoring program of drinking water reservoirs to generate foundational data for risk assessment and model evaluation; 2.) there is an industry task addressing model validation; and 3.) EFED is conducting a preliminary model evaluation of PRZM-EXAM predictions with existing monitoring data (www.epa.gov/pesticides/sap).

Cheminova Comment: Cheminova has concerns with EFED's reliance on GENEEC modeling to draw meaningful conclusions about potential aquatic risks associated with uses of ethyl parathion for a number of crops.

EFED Response: GENEEC exposure estimates are used in EFED's first-tier assessment of risk to aquatic organisms. If EEC's from GENEEC simulations exceed LOCs, the assessment is refined using EFED's second-tier exposure model, PRZM-EXAMS.

PRZM/EXAMS was run for a set of crops which spanned the range of labeled application rates for ethyl parathion. The GENEEC EECs are shown for crops for which PRZM/EXAMS modeling was not done. Further refinement of those values would likely result in EECs reductions. EFED did not use GENEEC results for the higher-tier ecological risk assessment. The risk characterization compares only PRZM/EXAMS EECs to toxicity endpoints.

Cheminova Comment: Cheminova does not understand why EFED persists in using GENEEC and PRZM/EXAMS modeling scenarios for its drinking water assessments when EFED has been told by outside experts (FIFRA Scientific Advisory Panel [SAP]) that these models are inappropriate for conducting drinking water assessments.

EFED Response: EFED has clearly stated the uncertainties of the modeling used in drinking water exposure assessments. The PRZM-EXAMS model scenario (10 ha field draining into a 20,000 L pond or commonly referred to as the "field pond" scenario) is being used as an interim tool because they have been used in estimating pesticide concentrations in aquatic environments. As presented in the July 29th, 1998 SAP, the drainage area to normal capacity (DANC), a potential factor representing reservoir vulnerability, in the PRZM-EXAMS runoff scenarios ("field pond") represents a 75th percentile DANC for all drinking water reservoir volumes of $\geq$ 5,000 m^3 volume (**www.epa.gov/pesticides**/sap). Based on this analysis, the DANC for the "field pond" is not overly conservative when compared to the DANC for larger reservoirs serving drinking water utilities. EFED conducted a comparison of contaminant predictions for the field pond scenario and an index reservoir, and predicted concentrations of hypothetical uses of selected pesticides were higher in the index reservoir.

However, when crop area factors were incorporated in the assessment, predicted index reservoir concentrations were slightly lower (by a factor of 0.3 to 0.5) than field pond predictions. EFED is refining the drinking water model approach to include the effect of crop area factor on predicted drinking water concentrations. EFED is open to the consideration of statistically representative, technically well conducted monitoring studies for use in exposure assessments.

EFED is developing an index reservoir scenario which reflects the physical construct of an actual drinking water reservoir. Additionally, EFED is evaluating basin-scale models for use in the drinking water assessment. Information on the index reservoir concept and basin-scale model evaluation was presented to the SAP on July, 29 1998.

Validation of the surface water models is problematic because there are insufficient data on pesticide concentrations in surface waters used as drinking water. EFED is addressing the model evaluation issues using the following approaches: 1.) OPP and USGS are conducting a pilot nationwide monitoring program of drinking water reservoirs to generate foundational data for risk assessment and model evaluation; 2.) there is an industry task addressing model validation; and 3.) EFED is conducting a preliminary model evaluation of PRZM-EXAM predictions with existing monitoring data (www.epa.gov/pesticides/sap).

EFED is currently moving towards a probabilistic approach for modeling that will enable increased consideration of a parameter's distribution, where available data are of sufficient quantity and quality, in the calculation of EECs. Until such time that EFED adopts a probabilistic drinking water assessment, EFED will continue to employ the current approach.

Finally, drinking water-based concerns, triggered by modeling results, typically lead to an evaluation of available water monitoring data. This was the case for methyl parathion.

B. SELECTION OF ENVIRONMENTAL FATE PARAMETERS

Cheminova disputes the environmental fate parameters used as input to the Tier II PRZM/EXAMS modeling. For each disputed parameter, Cheminova substitutes a much less conservative value for their modeling. Specifically, they make the following substitutions:

1. Soil Adsorption Constant (Koc): A Koc of 5000 was selected instead of the value of 816 ml/g used by EFED.

EFED Response: The Koc of 5000 used by the registrant is described in Hornsby, et al. (1996) as an estimate . An "estimate" value means either (a) an unusually wide range of values have been reported and we had no reason to select any one value as a 'best' value, or (b) no experimental value is available but a reasonable estimation was possible" or a value was "calculated from some more fundamental property". The Koc of 816 ml/g used by EFED was chosen based on experimental data submitted by the registrant. The registrant will repeat the adsorption-desorption laboratory study, because the soils in the original study were autoclaved.

The registrant stated that the United States Department of Agriculture (USDA) Pesticide Properties Database lists 13 different measurements of the Koc with a range from 350 ml/g to 34,674 ml/g. This shows that the Koc value of 816 ml/g used by EFED is conservative, but not unreasonable according to the data reported in open literature.

EFED stands by the use of a Koc of 816 ml/g until the new study results become available.

2. Aerobic Soil Metabolism: An aerobic soil metabolism of 32.8 days was selected instead of the value of 174 days used by EFED.

EFED Response: The registrant's submitted data (MRID 41187601) provides an aerobic soil metabolism half life of ~58 days(57.6 days). This half-life was multiplied by 3 (58x3=174 days) to provide the 90th percentile UCL of the mean as per interim guidance on model input parameters. The 90th percentile UCL of the mean is used in PRZM-EXAMS modeling in situations where only one half-life is available. This correction factor assumes that half-lives in different soils are normally distributed. The correction factor is used to incorporate uncertainty in the variability of the half-lives.

EFED is currently moving towards a probabilistic approach for modeling that will enable increased consideration of a parameter's distribution, where available data are of sufficient quantity and quality, in the calculation of EECs. Until such time that EFED adopts a probabilistic exposure assessment, EFED will use the 90^{th} percentile UCL of the mean in an attempt to be reasonable and protective of non-target populations.

3. Foliar Dissipation:

Cheminova Comment: EFED neglects to consider foliar dissipation for ethyl parathion in its PRZM simulation.

EFED Response: EFED did include foliar dissipation in the original EECs to the extent possible in the PRZM-EXAMS modeling. The model includes two input cards for foliar dissipation. The first, the "foliar extraction" card, regulates what mass fraction of the pesticide will wash off the leaves with a centimeter of rainfall. EFED sets this to 0.5 as a default.

The second input card is decay rate on foliage. Foliar decay data was not available for ethyl parathion. Foliar dissipation includes not only decay, but other processes such as washoff and volatilization. Therefore, the use of foliar dissipation in this input slot would account for decay, but double-count for foliar washoff. Therefore, it would have been inappropriate to use the foliar dissipation value in the model.

4. Application During Heavy Rainfall:

Cheminova Comment: In the PRZM model, the applications of ethyl parathion were assumed to occur on the same day in each year of the 36-year simulation. This has resulted, perhaps unintentionally, in applications during extreme rainfall events, which lead to abnormally high runoff levels. They believe that ethyl parathion would not be applied on days with substantial rainfall because of the possibility of foliar wash off. PRZM-EXAMS simulations should be "modified" to reflect application days with 3 cm of rainfall per day or less.

EFED Response: EFED agrees that ethyl parathion is not expected to be applied during or immediately before rainfall events. PRZM-EXAMS modeling, however, is a probabilistic assessment tool which captures the stochastic nature of rainfall patterns and subsequent runoff events over time. Additionally, PRZM has a minimum time step of a day (24 hours) which limits assessment of rainfall duration and intensity on time scales less than a day. Therefore, PRZM-EXAMS modeling results allow an probabilistic return frequencies (1:10 year) for estimated environmental concentrations (EEC) for a specific use site. EFED is interested in the registrant's scientific rationale for using 3 cm rainfall/per day or less as a cut-off for ethyl parathion application.

5. **Modeling of Buffer Strips:**

Cheminova Comment: Current ethyl parathion labels include a requirement of a 100-foot buffer zone from water bodies and property lines (unless written permission to apply is obtained). This situation is not considered in PRZM, which leads to exaggerated runoff contributions.

EFED Response: Cheminova is correct in pointing out that the 100-foot buffer is not incorporated into the PRZM runoff calculations. This adjustment, however, was considered a refinement regarding the contribution of spray drift on ethyl parathion deposition in the farm pond. EFED determined that the 100-foot buffer is expected to reduce the percent deposition spray by 60% when compared with the standard 5% spray drift assumption. The net effect of the buffer strip modeling is a reduction in the ethyl parathion loading, which corresponds to the use of a 100-foot buffer. The mitigatory effect of the buffer on loading from runoff cannot be quantified with current methods, although the buffer is likely to reduce aquatic EECs. Although this adds some uncertainty to aquatic risk conclusions, EFED's basic assessment of aquatic risk remains unchanged.

WATER MONITORING ASSESSMENT

1. Ground water:

Cheminova Comment: Cheminova disputes the use of SCI-GROW to derive a screening value of 1.21 ppb for drinking water derived from groundwater. Cheminova states that "this value represents a totally unrealistic estimate of groundwater EEC when compared to reliable ground water monitoring data". There is a considerable body of groundwater monitoring data from the United States Geological Survey, National Water-Quality Assessment (NAWQA) groundwater monitoring studies and from EPA's own Pesticides in Groundwater Database (PGWD; September 1992)

EFED Response: EFED believes the SCI-GROW screening value of 1.21 ppb for the acute and chronic drinking-water risk assessment. As stated in the RED chapter, EFED believes that 1.21 ppb is a reasonable, conservative estimate of possible acute concentrations of ethyl parathion that can be found in drinking water derived from ground water sources. Although the levels of detection of ethyl parathion in ground water were less than the model estimated value, EFED believes that the estimated value of 1.21 ppb is a conservative value that is protective of human health.

EFED did not request a ground-water monitoring study in the draft RED for ethyl parathion, and does not believe that such a study is necessary at this time. The screening value of 1.21 ppb has not been incorporated into HED's human-health risk assessment, as the estimated and observed surface-water concentrations described in the RED were higher. If, through further refinements to the risk assessment, ground water becomes the "risk driver" for ethyl parathion, EFED will revisit the issue. It is possible that ground-water monitoring studies would be called for in such a situation.

2. Surface Water

Cheminova Comment: The surface water bodies sampled by the NAWQA program are not direct drinking-water samples.

EFED Response: As indicated in the draft RED chapter, ethyl parathion is not on the Office of Water's regulated nor its unregulated contaminant monitoring lists. Therefore, public water supply systems are not required to analyze for it. As a result, EFED has relied on surface-water monitoring and simulation models in order to construct a conservative risk assessment protective of human health and the environment.

Cheminova Comment: "The extensive monitoring for ethyl parathion in surface water from NAWQA study sites across the United States for the years 1991-1996 indicates that any potential exposure to ethyl parathion in drinking water derived from surface water is extremely small."

EFED Response: EFED believes that current surface water monitoring data for ethyl parathion and ethyl paraoxon are not definitive in addressing exposure through drinking water because of the limited targeted monitoring data coupled with the inability to assess water treatment effects on ethyl parathion transformations. Therefore, the drinking water assessment will not be changed.

As stated in the RED, there are no monitoring data for ethyl parathion and its degradate ethyl paraoxon in finished drinking water. It is anticipated that water treatment processes such as disinfection (chlorination) may cause desulfonation of ethyl parathion with the formation of ethyl paraoxon. Nontargeted NAWQA monitoring data indicate sporadic detections of ethyl parathion (maximum concentration=0.14 ppb) in agricultural and urban surface waters. The concentration range of ethyl parathion in targeted monitoring studies from high ethyl parathion use areas was 0.9 to 2.5 ppb. However, the unique circumstances around these target monitoring studies (urban runoff or tile drain) limits a direct assessment of ethyl parathion transport under general row crop agriculture.

Cheminova Comment: Cheminova commented that the concentrations detected in the NAWQA surface-water monitoring study were significantly lower than predicted by PRZM-EXAMS modeling, because of the problems with the models and that the Agency should recognize the greater reliability of the surface water monitoring data compared to the modeling results.

EFED Response: EFED does not agree that this an indication of problems with the models. The NAWQA program is a national survey surface-water (and ground-water) monitoring program which was not designed to provide exposure data for ecological risk assessments. EFED does not believe that it is appropriate to derive risk quotients for non-target aquatic organisms using data from the NAWQA monitoring study. It is unrealistic to assume that results from a discrete simulation scenario in PRZM-EXAMS would precisely reflect the results of a national monitoring program.

If one focuses on the study areas which correspond with regions of high ethyl parathion usage, there is a wide disagreement between the maximum amount of ethyl parathion

detected within NAWQA, and the maximum concentrations simulated by PRZM-EXAMS. However, EFED does not believe that this is an indication that the modeling is of no use in risk assessment. Rather, use of the NAWQA data results in RQs that may not be sufficiently protective of non-target organisms for the following reasons:

- The 1-hectare pond is appropriate for assessing risk to non-target organisms; non-target aquatic organisms can be found in much smaller water bodies. The water bodies sampled in the NAWQA program range in size from drainage ditches to major waterways.

- Some of the samples in the NAWQA study were taken in areas of high ethyl parathion use. However, there is no way to relate detections of ethyl parathion to an actual application date. Whereas the PRZM-EXAMS model provides "day zero" concentrations to compare to the acute risk toxicity endpoints, the samples from the NAWQA study would not provide known, consistent data with relation to application dates.

Cheminova Comment: "Although EFED has stated that the USGS analytical method for water is weak for ethyl parathion, Cheminova believes it is acceptable for monitoring purposes. At concentrations greater than 0.1 ppb, the recovery is generally above 70 percent for surface water and reagent water. Recovery at lower concentrations and from groundwater is lower (54 to 57 percent), but still reproducible. USGS considers these ethyl parathion data reliable; otherwise, they would have designated the method as having poor performance and reported the data as 'estimated.'"

EFED Response: As stated in the RED, the average analytical recovery is 58% (SD=8%). Further analysis of the NAWQA field spike recovery data indicates that the ethyl parathion recovery in surface water at 0.1 ug/L appear to be better (median=101%) than reported in Zaugg et al, 1995 and earlier laboratory studies. However, there appears to be greater variability in ethyl parathion recovery in spiked field sample when compared with spike laboratory studies. Since the NAWQA data is predominately representative of concentrations < 0.1 ug/L (there was only one sample exceeding 0.1 ug/L), it is reasonable to assume that annual mean ethyl parathion concentrations in the NAWQA study are not expected to exceed 0.1 ug/L. However, the temporal sampling strategies used in the NAWQA program in conjunction with the non-targeted nature of the NAWQA sampling stations may restrict detection of peak concentrations of ethyl parathion in surface water.

NAWQA QA/QC indicate ethyl parathion recoveries in laboratory studies ranged from 58% (RSD=8) to 90% (RSD=6) in Reagent Water at concentrations from 0.03 to 1.0 ug/L, 68% (RSD=8%) to 68% (RSD=5%) in surface water from the South Platte River at concentrations from 0.1. and 1.0, and 54%(RSD=7%) and 57%(RSD=4%) in groundwater from the Denver Federal Center Well 15 at concentrations from 0.1 and 1.0 ug/L (Zaugg et al., 1995). Other USGS data indicate that field spike of ethyl parathion in 1493

samples at 0.1 ug/L had medium recovery of 101% with a range from 9% to 220% [written communication from Jeff Martin, USGS (9/3/99)]. In addition, there appears to be no detections of false negatives in control samples. However, there is more variability in the recovery of spiked field samples.

Cheminova Comment: EFED should use the 4-day concentration from modeling for the acute EEC, not the instantaneous.

EFED Response: Existing toxicological studies are very limited in their ability to distinguish between latent expression of adverse effects from short exposures and those effects requiring more protracted exposure for expression. In other words, the available toxicity studies can not determine how long organisms must be exposed before effects occur.

EFED will consider the use of the 96-hour predicted EECs in the calculation of acute RQs when available toxicological data demonstrate that exposures less than 96 hours do not result in adverse effects in the test organisms.

Cheminova Comment: "EFED indicates that it has a high degree of certainty concerning its conclusions about potential impacts of ethyl parathion on estuarine/marine fish and invertebrates." However, in addition to concerns Cheminova has with EFED's choice of model input parameters, the field pond scenario in the modeling "is not representative of estuarine/marine water bodies." This leads to "low confidence and high uncertainty" for the estuarine/marine assessments.

EFED Response: Although ethyl parathion is classified as "very highly toxic" to estuarine and marine fish, EFED agrees that the RED chapter should not claim a high degree of certainty in the risk to estuarine and marine fish. There is much uncertainty in using PRZM/EXAMS to estimate estuarine/marine exposure, hence it is not appropriate to claim a "high degree of certainty" for risk to estuarine and marine fish. Given the wide range of depths and flushing rates of estuaries, for instance, EFED cannot be sure whether values predicted by PRZM/EXAMS are underpredictions or overpredictions of potential exposure. In addition, EFED is not aware of estuarine or marine monitoring data that include detections of ethyl parathion at concentrations equivalent to the 9 ug/l acute LOC used in the risk assessment for estuarine and marine fish.

Despite the questions regarding use of PRZM/EXAMS to estimate estuarine EECs, the extremely high acute and chronic toxicity of ethyl parathion to estuarine and marine invertebrates suggests strongly that the insecticide poses significant risk to these organisms. EFED stands by its statement that there is high certainty in risk to estuarine and marine invertebrates when ethyl parathion is used near these habitats.

As detailed in an earlier comment response above, EFED does not agree with Cheminova's comment that EFED made "inappropriate choices for key model input

parameters."

Cheminova Comment: According to the draft EFED RED chapter, the only criterion EFED used for selecting a toxicity endpoint was to search the available data for the lowest toxicity value and then use that value for risk assessment. Cheminova believes that a more appropriate approach to data evaluation, particularly when a relatively large data set is available, involves consideration and utilization of the entire data set.

EFED Response: The EFED risk analysis is designed to assess risk to the most sensitive of the limited number of species tested in the laboratory, not to "typical" or "average" species. Our ecological risk assessments are founded on the assumption that if we protect the most sensitive tested species in the laboratory, then we provide some protection to the untested species in the environment. It is uncertain whether the "low-end" toxicity value is conservative enough, since untested species could very well be more vulnerable to pesticide exposure.

Comment: Cheminova used the Maximum Allowable Toxic Concentration (MATC) for their rebuttal assessment of chronic risk.

EFED Response: EFED uses the No Observed Adverse Effect Concentration (NOAEC) to establish endpoints for sublethal and chronic effects in fish and aquatic invertebrates, rather than the MATC. This has been adopted as EFED policy because: 1) the NOAEC is a more protective endpoint measure, and 2) the NOAEC is an empirically derived point against which to compare estimated concentrations. In addition, this value has been chosen because of the uncertainty in the MATC associated with extrapolating results across species, from laboratory to the field, from one effect to another, and from one generation to another.

Cheminova Comment: Many citations in the draft RED chapter did not have accompanying entries in the list of references.

EFED Response: EFED will provide full references for these citations. The majority of "missing" citations are identified in the draft RED by an MRID number, which identifies a document within EPA's files.

D. DATA REQUIREMENTS

Guideline #*162-1:* Aerobic Soil Metabolism

Cheminova Comment: "The draft EFED RED chapter concludes that two submitted studies (MRID 41187601 and 42073101) provide acceptable data to fulfill the Guideline 162-1 data requirement."

EFED Response: The draft EFED RED chapter stated that the two submitted

studies (MRID 41187601 and 42073101) provide acceptable data to fulfill the Guideline 162-1 data requirement. However, upon further evaluation of the data, EFED decided that the data provide upgradable supplemental data at this time. These data can be upgraded with the submission of the following information:

a) Sample storage conditions need to be specified
b) Storage stability data for paraoxon are needed
c) Kinetic analysis is required to assess the degradation rate of total (extractable plus nonextracable) ethyl parathion
d) The registrant should provide a complete assessment on the presence of ethyl paraoxon in the submitted studies.

Guideline #*162-3:* Anaerobic Aquatic Metabolism

Cheminova Comment: "The original study was conducted at a dose rate of 9.83 ppm in flooded soil, at a time-averaged temperature range of 24.0 ^{0}C to 25.7 ^{0}C during the year-long study. The temperature extremes mentioned in the draft RED chapter, 19.2 ^{0}C and 27.8 ^{0}C, were temperature spikes that lasted for less than 2 hours. Therefore, it is unfair to use these short-term extremes in judging the study's acceptability."

EFED Response: The study was deemed supplemental for a number of reasons among them the inadequate verification of storage stability results and the discrepancies between the results of the TLC and HPLC analysis.

Cheminova Comment: "The Agency has several major concerns about the qualitative and quantitative aspects of these studies. Because these studies were conducted at relatively high rates, approximately 10 ppm, the Agency should not require identification of degradates down to the 0.01 ppm level (0.1 percent of applied in this case), but rather should use the 10 percent of applied rule for requiring degradate identification."

EFED Response: Degradates of known toxicological or ecotoxicological concern such as ethyl paraoxon must certainly be identified and quantified even if they are present at <10% of the dose rate.

Cheminova Comment: the studies (MRID 41249801 and 42451001) should be acceptable because they adequately describe the rates and routes of degradation of ethyl parathion in anaerobic aquatic environments. No unidentified degradate, other than unextractable radiocarbon and radiocarbon remaining at the origin after TLC analysis, reached levels greater than 10 percent of applied radioactivity.

EFED Response: The studies (MRID 41249801 and 42451001) did not satisfy the requirements but provided supplemental data on the anaerobic aquatic metabolism of ethyl parathion. The data were deemed supplemental because there were analytical discrepancies between the results of TLC and HPLC methods for ethyl parathion degradation products (mainly ethyl paraoxon) and inadequate verification of storage stability studies.

Guideline #*162-4:* Aerobic Aquatic Metabolism

Cheminova Comment: "Because the aerobic aquatic studies were conducted at relatively high rates (approximately 10 ppm), Cheminova believes that the Agency should not require identification of degradates down to the 0.01 ppm level (0.1% of applied in this case), but rather should use the 10% of applied rule for requiring degradate identification."

EFED Response: Degradates of known toxicological or ecotoxicological concern such as ethyl paraoxon must certainly be identified and quantified even if they are present at <10% of the dose rate.

Cheminova Comment: "Comparison of the results of TLC versus HPLC analyses of the 10-day sample shows good agreement with one exception. The TLC origin material is apparently not equivalent to the fraction labeled unknown in the HPLC analysis but is the major portion of this fraction. It is likely that the unknown HPLC fraction as well as the TLC origin fraction are both comprised of multiple degradates. With this in mind, the agreement between TLC and HPLC results is acceptable."

EFED Response: The registrant statement itself admits that there are discrepancies between the results of the TLC and HPLC analyses of the 10-day sample. Furthermore, the HPLC analysis of the soil extracts from day 5, 21, and 31 post treatment samples indicated that ethyl paraoxon comprised a total of 11.4, 21.0, and 17.3 % of the applied, respectively. However, as determined by TLC, the peak tentatively identified as ethyl paraoxon was not present in the soil extract. Also, there was no 4-nitrophenol identified by HPLC in day 14 water samples where as 4-nitrophenol comprised 7.84 % of the applied as determined by TLC.

Guideline #*164-1:* Terrestrial Field Dissipation

Cheminova Comment: "Cheminova believes the terrestrial field dissipation studies are fully acceptable, that they confirm the very short soil half-life of ethyl parathion under a variety of agricultural use patterns , and that qualitatively, they confirm the aerobic soil metabolism study."

EFED Response: The terrestrial field dissipation studies provided supplemental data on the dissipation of ethyl parathion. The studies were deemed as supplemental data because 1.) the dissipation of 4-nitrophenol and O,O-bis (4-nitrophenyl) ethylphosphate were not addressed in the studies and 2.) storage stability studies indicate paraoxon may not be stable during soil sample storage. These deficiencies limit interpretation on the rates and routes of dissipation for ethyl parathion degradates.

Guideline #*165-4:* Accumulation in Fish

Cheminova Comment: "On July 1, 1991, Cheminova submitted a metabolite characterization and identification report (SLI Report Number 9 1-02-3664, MRID 41930001) as a supplement to the initial pharmacokinetic portion of the bioaccumulation study. Apparently EFED has failed to review this data submission. EFED should review this submission and provide Cheminova with a DER. Cheminova believes the original and supplemental submissions fully satisfy the fish bioaccumulation data requirement."

EFED Response: The accumulation in fish study (MRID 41930001) was reviewed by EFED and was deemed supplemental due to: 1) the ambiguities in the analytical methods and 2) the lack of data on the concentration of ethyl parathion and it's degradates in exposure water. A DER dated December 9,1998 was sent to Cheminova through SRRD.